UNITED STATES DISTRICT COURT **(ECF)**
SOUTHERN DISTRICT OF NEW YORK

IN RE: FOSAMAX PRODUCTS LIABILITY LITIGATION	MASTER FILE MDL NO. 1789 1:06-MD-1789 (JFK) (JCF)
This Document Relates To All Actions	MEMORANDUM AND ORDER

JAMES C. FRANCIS IV
UNITED STATES MAGISTRATE JUDGE

This is a multidistrict litigation that was consolidated in this district for purposes of discovery. The plaintiffs, through the Plaintiffs' Steering Committee, allege that the prescription drug Fosamax, manufactured by Merck & Co., caused adverse effects, in particular, osteonecrosis of the jaw. During discovery, the plaintiffs subpoenaed Dr. Bruce M. Psaty, who participated in a drug safety report issued by the National Academy of Sciences (the "Academy"). Dr. Psaty now moves to quash the subpoena pursuant to Rule 45(c)(3) of the Federal Rules of Civil Procedure.

Background

A. Factual History

The Academy is a private, non-profit corporation charted by Congress in 1863. See 36 U.S.C. §§ 150301-150304. It is dedicated to furthering science for the general welfare. (Declaration of Dr. E. William Colglazier dated December 19, 2008 ("Colglazier Decl."), attached as Exh 3 to Dr. Bruce M. Psaty's Motion to Quash Third Party Subpoena ("Motion to Quash"), ¶ 6). Often commissioned by

U.S. government agencies, the Academy establishes committees to conduct research and assess issues of scientific concern, including public health. (Colglazier Decl., ¶¶ 6, 9). The Committee on the Assessment of the U.S. Drug Safety System (the "Drug Safety Committee") was one of the committees established by the Academy's Institute of Medicine. (Declaration of Dr. Kathleen Stratton dated December 19, 2008 ("Stratton Decl."), attached as Exh. 2 to Motion to Quash, ¶¶ 3, 5). The Drug Safety Committee was created at the request of the U.S. Food and Drug Administration (the "FDA") to conduct an independent assessment of drug safety in the United States. (Stratton Decl., ¶ 5).

In 2004, the Academy asked Dr. Psaty to serve on the Drug Safety Committee. (Motion to Quash at 2). He accepted, knowing that, like all Committee members, he would not be compensated for his work. (Stratton Decl., ¶ 4). Dr. Psaty served on the Drug Safety Committee for 15 months between 2004 and 2006. (Motion to Quash at 2).

During his tenure, Dr. Psaty participated in a detailed examination of the current drug safety system in the United States. (Stratton Decl., ¶ 7). In September 2006, the Committee released its findings in a detailed report, "The Future of Drug Safety: Promoting and Protecting the Health of the Public" (the "Drug Safety Report"). (Drug Safety Report, attached as Exh. 4 to Motion to Quash). This 317-page report contains recommendations for

improving national drug safety, many of which involve proposals to change the structure and activities of the FDA's Center for Drug Evaluation and Research. (Stratton Decl., ¶ 7). The report did not focus on any single drug or category of pharmaceuticals. (Drug Safety Report at 25-26). In particular, it did not study Fosamax.

B. Procedural History

The Plaintiffs' Steering Committee served Dr. Psaty with a deposition subpoena on December 1, 2008. (Subpoena of Bruce Psaty, M.D., Ph.D., attached as Exh. 1 to Motion to Quash). On December 22, 2008, Dr. Psaty filed this motion to quash in the United States District Court for the Western District of Washington. Thereafter, a United States Judicial Panel on Multidistrict Litigation denied Dr. Psaty's request to vacate a previous decision to include this case among the actions consolidated for discovery in this district. (Transfer Order dated June 9, 2009 at 1). The motion to quash is therefore before this Court for determination.

Discussion

A. Rule 45(c)(3)

Under Rule 45(c)(3), a subpoena may be quashed if it requires "disclosing a trade secret or other confidential research, development, or commercial information." Fed. R. Civ. P. 45(c)(3)(B)(i). The plaintiffs argue that they "[do] not seek to discovery [sic] confidential information about the deliberations of the committee." (Plaintiff Steering Committee's Response to Dr.

Psaty's Motion to Quash Third Party Subpoena ("Plaintiffs' Memo.") at 2). Instead, they contend that they merely seek to reduce public statements made by Dr. Psaty to "testimonial format." (Plaintiffs' Memo. at 2).

As the parties' representations about what might be asked during deposition differ, it is unclear whether the subpoena of Dr. Psaty would in fact elicit confidential information. This thus creates a degree of uncertainty as to whether Rule 45 on its face provides a sufficient basis for quashing the subpoena. Rule 26(c), however, potentially provides a complementary source of authority. Indeed, the Advisory Committee Notes state that Rule 45(c)(3)(B)(i), which "protect[s] . . . from unnecessary or unduly harmful disclosures of confidential information[,]. . . corresponds to Rule 26(c)." Fed. R. Civ. P. Rule 45 advisory committee's notes (1991); see also Insulate America v. Masco Corp., 227 F.R.D. 427, 432 (W.D.N.C. 2005)("A non-party . . . may seek from the court protection from discovery by the overlapping and interrelated provisions of Rules 26 and 45 . . . ."). Thus, I must consider not only Rule 45, but also Rule 26(c).

B. Rule 26(c)

Rule 26(c) allows courts to issue an order "to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense . . . ." Fed. R. Civ. P. 26(c). In analyzing motions for a protective order, courts weigh the need of the party

seeking the discovery against any undue hardships created by permitting it. See In re Initial Public Offering Securities Litigation, 220 F.R.D. 30, 36 (S.D.N.Y. 2003); Apex Oil Co. v. DiMauro, 110 F.R.D. 490, 496 (S.D.N.Y. 1985). Because relevant evidence carries a presumption of admissibility, the burden of proof for a Rule 26(c) order rests with the party seeking protection. See Condit v. Dunne, 225 F.R.D. 100, 106 (S.D.N.Y. 2004). Ultimately, if the court finds that undue hardships outweigh necessity, it may quash the subpoena altogether or enforce it on limited terms or with other conditions. See Fed. R. Civ. P. 26(c); American High-Income Trust v. AlliedSignal Inc., No. 02 Civ. 2506, 2006 WL 3545432, at *2 (S.D.N.Y. Dec. 8, 2006).

1. Relevance

As a threshold matter, the evidence sought to be discovered must be relevant. See Condit, 225 F.R.D. at 105-06. The Federal Rules of Evidence defines relevant evidence as "evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Fed. R. Evid. 401. Thus, the threshold for establishing relevance is minimal. See United States v. Khan, 787 F.2d 28, 34 (2d Cir. 1986); see also Condit, 225 F.R.D. at 105 ("Although not unlimited, relevance, for purposes of discovery, is an extremely broad concept.").

Here, Dr. Psaty allegedly made public comments in connection

with his participation on the Drug Safety Committee. (Plaintiffs' Memo at 2). As noted above, the study did not investigate Fosamax or any other commercial drug, nor did it study the potential adverse effects of any particular drug. (Drug Safety Report at 25-26). Rather, it issued recommendations about improving national drug safety and procedures of the the FDA's Center for Drug Evaluation and Research. (Stratton Decl., ¶ 7). At best, the information sought from Dr. Psaty is tangentially related to the plaintiffs' allegations that osteonecrosis is caused by Fosamax. Indeed, the plaintiffs do not even specify the public comments of Dr. Psaty that they hope to reduce to a form admissible at trial. But, because the threshold for demonstrating relevance is low, I will assume that the plaintiffs have met it and will proceed to weigh necessity and hardship.

2. Necessity

The first step of the balancing inquiry is to determine the necessity of the evidence to the party seeking discovery. It is a question of degree, and a strong showing of necessity may overcome a claim of substantial hardship. See Dow Chemical Co. v. Allen, 672 F.2d 1262, 1270 (7th Cir. 1982). In measuring a party's need for evidence, courts look to a variety of factors, including the need to prepare an adequate defense or establish a claim, the availability of alternative evidence, the need to cross-examine expert witnesses, and the need for underlying data. See Deitchman

v. E.R. Squibb & Sons, Inc., 740 F.2d 556, 561-63 (7th Cir. 1984); In re: Silicone Gel Breast Implants Products Liability Litigation, No. CV 92-P-10000S, 1996 WL 1358526, at *2 (N.D. Ala. April 11, 1996); Plough Inc. v. National Academy of Sciences, 530 A.2d 1152, 1159 (D.C. App. 1987).

In the present case, the plaintiffs have failed to demonstrate a need for Dr. Psaty's testimony. The subpoena is solely based on a desire to "reduce . . . to testimony" some of Dr. Psaty's public statements. (Plaintiffs' Memo. at 2, 7). The plaintiffs have not claimed that alternative evidence is unavailable. They do not assert any need to obtain the underlying data used to produce the conclusions in the Drug Safety Report. There is no showing that Dr. Psaty's testimony is needed to cross-examine experts nor to establish a claim. As a result, the plaintiffs have not demonstrated a substantial need for deposing Dr. Psaty.

3. Undue Burden

Discovery may be blocked if permitting it would create an undue burden that outweighs its necessity. See Solarex Corp. v. Arco Solar, Inc., 121 F.R.D. 163, 169 (E.D.N.Y. 1988). The burden encompasses both the personal hardship to the subpoenaed party and the wider social consequences of permitting discovery. See id.

a. Personal Hardship

Personal hardship would result if Dr. Psaty were compelled to testify. In general, third parties are afforded more sympathy in

weighing the burden of discovery because they have no personal stake in the litigation. See Fears v. Wilhelmina Model Agency, Inc., No. 02 Civ. 4911, 2004 WL 719185, at *1 (S.D.N.Y. April 1, 2004). Moreover, courts are wary of compelling testimony from third party researchers because it risks inadvertent disclosure of protected information. See Dow Chemical, 672 F.2d at 1276; Solarex Corp., 121 F.R.D. at 179-80. Any accidental disclosure could disrupt a researcher's relationships at work and even jeopardize his career. See Dow Chemical, 672 F.2d at 1276.

Here, Dr. Psaty has no interest in the litigation. Forcing his appearance at a deposition carries the risk of disclosing his role in private, internal matters of the Academy. Under these circumstances, Dr. Psaty would suffer personal hardship if the subpoena is upheld.

b. Social Consequences

While upholding the subpoena would create hardship for Dr. Psaty, the resulting social impact would be far more serious. Compelling testimony from a third party researcher risks chilling participation in beneficial public research. See Dow Chemical, 672 F.2d at 1273-76; Plough, 530 A.2d at 1156-57. There is a serious danger that permitting discovery in these situations "inevitably tend[s] to check the ardor and fearlessness of scholars, qualities at once so fragile and so indispensable for fruitful academic labor." Sweezy v. New Hampshire, 354 U.S. 234, 262 (1957).

In Plough, the court addressed this potential chilling effect. See Plough, 530 A.2d at 1156-58. There, defendant Plough Inc., a pharmaceutical manufacturer, faced allegations that its aspirin caused the plaintiff to develop Reye Syndrome. Id. at 1154. To support these claims, the plaintiff cited a government study validated by the Academy. Id. Plough then subpoenaed the Academy, seeking documents reflecting confidential deliberations and preliminary drafts underlying the Academy's review. Id. In upholding the lower court's decision to quash the subpoena, the court credited the Academy's claim that its "ability to convince volunteers to serve on its committees would be impaired, since individuals would be reluctant to serve if they knew their comments were subject to disclosure." Id. at 1156-57. The court further reasoned that

> [e]ven limited disclosure of the preliminary conclusions, hypotheses, thoughts and ideas ventured by Committee members prior to their being tested and criticized would not only embarrass those members, it would discourage members of [Academy] committees in the future from expressing themselves freely during their deliberations, and might cause some potential volunteers to refrain from participating in [Academy] studies altogether.

Id. at 1157-58. Because the potential chilling effect significantly outweighed the need, the court upheld the decision to quash the subpoena. See id. at 1160.

Other courts, too, have acknowledged the gravity of this type of potential chilling effect. See Dow Chemical, 672 F.2d at 1276 (upholding refusal to enforce subpoena duces tecum because

researchers "with the knowledge throughout continuation of their studies that the fruits of their labors had been appropriated by and were being scrutinized by a not-unbiased third party . . . carries the potential for chilling . . . ."); Richards of Rockford, Inc. v. Pacific Gas & Electric Co., 71 F.R.D. 388, 390 (N.D. Cal. 1976)(quashing subpoena of third party research assistant because "[c]ompelled disclosure of confidential information would without question severely stifle research into questions of public policy, the very subjects in which the public interest is greatest."); Apicella v. McNeil Laboratories, Inc., 66 F.R.D. 78, 85 (E.D.N.Y. 1975)(denying discovery of identity of third party author of scientific report because "if [research] consultants were forced to participate in searching cross-examinations, often resulting in embarrassment and inconvenience, they would hesitate to act as sources in the future, to the detriment of the medical community and the public.").

Like the cases cited above, subpoenas of third party researchers at the Academy raises serious concerns. The Academy is a public, non-profit corporation dedicated to furthering science, the general welfare, and public health. (Colglazier Decl., ¶ 6). It relies heavily on the candor of its committee members to ensure the free exchange of ideas paramount to producing the best reports. (Colglazier Decl., ¶¶ 13, 18). As such, participants are assured that their research and reviews are confidential. (Colglazier

Decl., ¶ 13). For participants like Dr. Psaty, who was not compensated for his work, compelling testimony about internal committee matters would chill the crucial atmosphere of candor. Further, it would handicap the Academy's ability to recruit participants, who may fear the potential for embarrassment associated with questioning in connection with litigation.

Of course, the plaintiffs deny any intention of eliciting confidential information. Taken at their word, the plaintiffs contend that they only need testimony from Dr. Psaty to reduce certain public statements to testimony. If this is truly the case, while the personal and social hardships would be minimized, the plaintiffs' showing of necessity is virtually nil. Alternatively, if the plaintiffs actually want more from the deposition than they assert, the corresponding undue burden would predominate because, as discussed above, the subpoena would risk chilling participation in beneficial public research. Thus, regardless of the plaintiffs' intent, the subpoena presents an undue burden that outweighs the necessity for testimony.

C. Protective Measure

Once Rule 26(c) balancing merits protective measures, courts have discretion in deciding what form of protection to grant. See Fed. R. Civ. P. 26(c). In general, the subpoenaed party is entitled to complete protection when the undue burden significantly outweighs necessity. See Plough, 530 A.2d at 1160. Conversely,

when it is possible to limit discovery to materials outside the scope of 26(c) protection, a qualified protective order should be granted. See Deitchman, 740 F.2d at 564 (finding that defendant was entitled to limited discovery despite need to protect certain requested material). However, if limiting discovery is impossible or creates a risk of disclosure of the protected materials, blanket protection is appropriate. See Dow Chemical, 672 F.2d at 1278 (affirming refusal to enforce subpoena because limited discovery would reduce, but not eliminate, risk of disclosure). Indeed, even a perceived risk of disclosure may merit blanket protection when there is a potential chilling effect. See Solarex, 121 F.R.D. at 180.

In the case of Dr. Psaty, the undue burden significantly outweighs the plaintiffs' need for discovery, which weighs in favor of blanket protection. While the plaintiffs have disclaimed any intention to ask Dr. Psaty about internal Academy matters, their vaguely asserted need creates considerable uncertainty over what information they seek. This creates a danger that the deposition would lead to inadvertent disclosures of protected information. And, even if there is a guarantee that discovery will be appropriately limited, the perception of intrusion into the domain of the Academy would carry a substantial risk of chilling. As a result, quashing the subpoena is the most appropriate protective measure in this case.

Conclusion

For the reasons set forth above, Dr. Psaty's motion is granted, and the subpoena shall be quashed.

SO ORDERED.

James C. Francis IV

JAMES C. FRANCIS IV
UNITED STATES MAGISTRATE JUDGE

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